STATEMENT OF

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ON BEHALF OF

PURDUE PHARMA L.P.

BEFORE THE

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OF THE COMMITTEE ON GOVERNMENT REFORM

U. S. HOUSE OF REPRESENTATIVES

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MADAM CHAIRMAN:

Thank you for giving me the opportunity to submit testimony for this hearing on behalf of Purdue Pharma L.P., the distributor of OxyContin® (oxycodone HCl controlled-release) Tablets. For almost five years, addressing the diversion and abuse of OxyContin has been one of Purdue's top priorities. The FDA has approved OxyContin for a medical purpose for those patients who need it (see attached professional prescribing information). Tragically, there also has been illegal trafficking and abuse of OxyContin in some regions of the country where it has become part of the much larger, historical problem of the abuse of prescription medicines. For example, much of Massachusetts, Kentucky, West Virginia and Florida lie within federally designated High Intensity Drug Trafficking Areas, with HIDTA designation dates ranging from 1990 to 2001. While there is no easy solution that will prevent the abuse of prescription medications while still ensuring their availability to patients with legitimate medical need, Purdue Pharma, more than any other pharmaceutical company, is working on solutions to this complex problem.

I would like to address allegations that Purdue's marketing of OxyContin has contributed to the illegal trafficking and abuse of the medication. I would also like to highlight some of the Company's efforts to combat this problem.

On December 23, 2003, the General Accountability Office (GAO) issued a report titled "PRESCRIPTION DRUGS: Factors That May Have Contributed to OxyContin Abuse and Diversion and Efforts to Address the Problem." After a lengthy and comprehensive investigation, the GAO confirmed that there is no easy solution to, and that no one factor can be blamed for, the abuse and illegal trafficking of OxyContin. The GAO report made some important findings:

- One of the primary questions posed to the GAO was: *"Is there a direct correlation between the marketing strategies of the drug [OxyContin] and its excessive abuse?"* Following an in-depth investigation over a two-year period, the GAO was unable to establish such a correlation.

- The GAO pointed out that the Food and Drug Administration (FDA) approved OxyContin in 1995 amid heightened awareness that many people were suffering from undertreated pain. It was in that context that Purdue's marketing efforts contributed to rapidly increasing sales. According to the GAO, "Fortuitous timing may have contributed to this growth." (p. 9)

- The GAO recognized that when it was approved, both Purdue and the FDA knew the abuse potential of OxyContin, but could not anticipate the extent of diversion and abuse that was to emerge. The GAO noted that, although OxyContin was classified by the federal government as a Schedule II controlled substance with a high potential for abuse, "FDA officials said when OxyContin was approved the agency believed that the controlled-release formulation would result in less abuse potential because, when taken properly, the drug would be absorbed slowly, without an immediate rush or high." (p. 29). According to the GAO, "FDA officials stated that neither they nor other experts anticipated that crushing the controlled-release tablet and intravenously injecting or snorting the drug would become widespread and lead to a high level of abuse." (p. 30)

- The GAO identified several factors that may have made OxyContin an attractive target for abuse and diversion:

    - OxyContin's controlled-release formulation, which made the drug beneficial to patients, enabled the drug to contain more of the active ingredient oxycodone than non-controlled-release opioid products.
    - The safety warning on the OxyContin label directed to health care professionals about taking the tablets intact could have unintentionally provided abusers with information on how to obtain the rapid release of oxycodone by crushing or chewing the tablet.
    - While the GAO noted that the increased availability of OxyContin in the marketplace may have increased the opportunities for diversion and abuse, the GAO specifically noted that the historic predisposition of certain areas to prescription drug abuse may have contributed to OxyContin diversion and abuse, particularly when coupled with the profit potential resulting from the illicit sale of OxyContin. (p. 32).
    - The GAO report also states that, according to the Drug Enforcement Administration, while OxyContin is "a drug of choice among abusers, OxyContin has not been and is not now considered the most highly abused and diverted prescription drug nationally" (p.33). More current federal data from the Substance Abuse and Mental Health Services Administration indicate that, while OxyContin continues to be abused, it is not the number one opioid-containing medication that is abused, nor are the opioid medications as a group the only drugs abused with any frequency.

- The GAO acknowledged Purdue's efforts to combat the problem: "After learning about the initial reports of abuse and diversion of OxyContin in Maine in 2000, Purdue formed a response team made up of its top executives and physicians to initiate meetings with federal and state officials in Maine to gain an understanding of the scope of the problem and to devise strategies for preventing abuse and diversion." (p. 10).

Having identified some factors that, in retrospect, may have contributed to diversion and abuse, but recognizing that they had not been a primary concern at the time of approval because the FDA and Purdue were focusing on the legitimate use of OxyContin as a pain medication, the GAO reached this conclusion: "Addressing abuse and diversion problems requires the collaborative efforts of pharmaceutical manufacturers; the federal and state agencies that oversee the approval and use of prescription drugs, particularly controlled substances; the health care providers who prescribe and dispense them; and law enforcement." (p. 42)

Purdue has been working to establish this type of collaborative approach ever since it became aware of the problem. Testifying on August 28, 2001 before a field hearing of the House Commerce Committee's Subcommittee on Oversight and Investigations, Michael Friedman, who is now Chief Executive Officer and President of Purdue Pharma, confirmed Purdue's commitment to addressing the problem through a collaborative effort, as follows:

> "Solving the problem of drug abuse requires the cooperation of many elements in our community: law enforcement, the schools, religious institutions, parents and family, the courts, the medical community, the press, federal and state legislators, government agencies, social services providers, and the pharmaceutical industry. Purdue is trying to help through our specific programs and our cooperation with the other elements in the community. Prescription Monitoring Programs can reduce doctor shopping and diversion from medical practices. Tamper resistant prescriptions can reduce copying or alteration. Education of responsible doctors can arm them with the tools they need to stop diversion from their practices. A better information system can allow us to know where abuse and diversion is cropping up and allow medical education and law enforcement to act earlier to "nip these problems in the bud." Development of abuse resistant products can reduce the incidence of abuse. What is needed is cooperation and common purpose. This is a long-standing societal problem that requires a reasoned solution."

The extent of the abuse and diversion of OxyContin, although unanticipated, is a matter of serious and special concern to Purdue. Once Purdue recognized the problem; it launched a comprehensive program to combat the abuse and diversion of OxyContin, much of which is part of its risk management program. To date, these initiatives include:

- Distributing approximately a quarter of a million free, tamper-resistant prescription pads to more than 16,000 doctors;
- Working with federal, state and local law enforcement to support and enhance their drug diversion investigations;
- Educating teens and parents about the dangers of prescription abuse through the Painfully Obvious® awareness and education program;

- Supporting community based anti-drug programs in numerous communities, in conjunction with "Communities That Care® and the Community Anti-Drug Coalitions of America;
- Creating RxPATROL™, a shared database to assist law enforcement in apprehending pharmacy robbers;
- Intensifying efforts to help healthcare professionals recognize and reduce abuse and diversion;
- Implementing the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System, a national surveillance program that tracks the incidence of abuse and diversion of selected opioid analgesics; and
- Working with state legislators and members of Congress to develop legislation that would help states implement prescription monitoring programs that can help reduce diversion by doctor shopping. Purdue's efforts have led to several states adopting PMP legislation and the company was instrumental in helping the federal NASPER legislation become law, which will provide for federal support for the purpose of creating or improving state PMPs.
- Investing more than $200 million in research to develop more abuse-resistant opioid analgesics that offer patients safe and effective pain control, while being undesirable to those who would abuse them.

I will take this opportunity to address the mistaken perception that developing an abuse-resistant opioid pain medication can be easily accomplished and that Purdue is not committed to this effort. On the contrary, the development of a pain medication that is safe and effective for patients with pain and also resistant to tampering by drug abusers is extremely challenging work. According to an article in the Washington Post, more than 450 patent applications have been filed relating to processes to develop abuse-resistant pain medications and at least 19 companies are engaged in this type of research. However, to date, no company has successfully brought an abuse-resistant medication to market. The Post article includes a statement from Martin Adler, Executive Director of the College on Problems of Drug Dependence, who puts this matter into proper perspective: "If this was easy to do, it would have been done long ago."

The GAO recognized that in response to concerns about diversion and abuse of OxyContin, the FDA and Purdue collaborated in developing a risk management program to help detect and prevent diversion and abuse. The report recommends that FDA guidance to the pharmaceutical industry include such programs to manage risk with New Drug Applications for Schedule II controlled substances. Purdue strongly endorses that recommendation. At least four companies now marketing generic forms of OxyContin have captured 70 percent of the controlled-release oxycodone market with their products, and other companies are marketing other Schedule II opioid analgesic products. The elements of the risk management programs for many of these Schedule II analgesics, if they exist at all, are not publicly available.

Purdue Pharma voluntarily designed what we believe is one of the most comprehensive Risk Management Programs (RMP) put forth by the industry for a medication of this type. This RMP is intended to facilitate proper patient selection, reduce abuse, minimize diversion, and avoid other improper uses of OxyContin Tablets. The RMP includes extensive medical education, sales force training, detailed prescribing information, epidemiological surveillance of

opioid analgesic diversion and abuse, and provisions for intervening in areas where diversion or abuse of opioid analgesics has been identified as occurring . Specifically:

- The professional prescribing information contains clear and strong warnings, including a prominent boxed warning, for prescribers, pharmacists, and other healthcare professionals.

- Educational programs are provided to healthcare professionals regarding assessment, treatment, and evaluation of patients suffering from persistent pain. These programs have been provided on an ongoing basis, particularly in areas with high levels of abuse of prescription medicines.

- Surveillance of the rates of diversion and abuse is being conducted through the company's RADARS® System.

- When surveillance reveals abuse, appropriate interventions are initiated. Interventions may include, but is not limited to, notification of health care professionals and law enforcement in the affected area, with offers of what our company has available to mitigate the problems, as outlined above.

- The company has implemented a state of the art supply chain security systems to combat diversion from the distribution chain and pharmaceutical counterfeiting.

- Additionally, Purdue supports efforts to regulate Internet pharmacies in an effort to curb diversion and abuse of controlled substances

It must be noted that no RMP will be able to completely eliminate abuse, diversion, pediatric use, improper patient selection or other unintended uses of OxyContin or any other medicine.

Purdue believes that the GAO report should put to rest the often-repeated assertion that Purdue's marketing is somehow responsible for the illegal diversion and the abuse of OxyContin. At a hearing of the Senate's Health, Education, Labor and Pensions Committee on February 12, 2002, Senator Dodd insightfully asked: "How do you address illicit use by going after targeting and promotion of a product that is supposed to be used legally?" He continued, "I do not understand the connection between illegal use and marketing and promotion. I do not see the connection." (Hearing transcript, p. 93) As noted in the GAO report, some prescription drugs, hydrocodone combinations, for example, are more abused than OxyContin, notwithstanding the fact that most companies that sell them do virtually no promotion. The prescription drug increasingly mentioned in the press and highlighted in the Senate Government Affairs hearing in the summer of 2003 as a drug of abuse, methadone, is also not actively promoted.

In fact, in the lawsuits where Purdue has been accused of "aggressive" marketing, we have to date had 365 such suits dismissed or decided in our favor, and none have been lost or settled. In a Kentucky case, the United States District Judge wrote in her opinion (Foister et al. vs. Purdue Pharma L. P., et al):

> "The plaintiffs' theory…appears to be based on the argument that additional restrictions on the marketing, promotion, and prescription of OxyContin will (i) reduce the overall quantity of OxyContin prescribed, which in turn will (ii) reduce the overall quantity of OxyContin available for illegal diversion, which in turn will (iii) reduce the likelihood that purported class members, or the general public, will illegally obtain OxyContin. As a matter of law, this theory is too speculative, hypothetical, and devoid of record proof...."

The court further stated:

> "The plaintiffs have failed to produce any evidence showing that the defendants' marketing, promotional, or distribution practices have ever caused even one tablet of OxyContin to be inappropriately prescribed or diverted."

Despite considerable litigation since then, no court has found otherwise.

No one can seriously think that Purdue is marketing OxyContin to criminal traffickers and drug abusers. The company does not engage in direct-to-consumer marketing for OxyContin. Purdue only markets OxyContin to health care professionals. By and large, the patients being treated by those health care professionals are not abusing this medicine -- iatrogenic addiction to opioids, although not well studied, is rare. It is not Purdue's marketing to doctors who treat patients with pain that creates the problem we are all concerned about. It is the illegal trafficking of these medications and the societal problem of substance abuse.

Since this hearing is being held in Boston where the media has written extensively about the abuse of OxyContin, I would like to join with local health care professionals who have raised concerns that sensational and inaccurate media coverage has jeopardized the availability of OxyContin and similar prescription drugs to patients who need them. Certainly there is an important and appropriate role for news reports that bring attention to illegal trafficking and abuse of prescription medications. But care must be taken to recognize that the very same medications are absolutely indispensable to many patients with pain.

I hope that this testimony demonstrates Purdue's commitment to combating the illegal trafficking and abuse of prescription medications and our concern that patients with pain continue to have access to appropriate treatment, including when medically necessary, prescription pain medications like OxyContin Tablets.

The professional product labeling for OxyContin® Tablets contains the following **boxed warning:**

WARNING:

OxyContin is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine.

Oxycodone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OxyContin in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

OxyContin Tablets are a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

OxyContin Tablets are NOT intended for use as a prn analgesic.

OxyContin 80 mg and 160 mg Tablets ARE FOR USE IN OPIOID-TOLERANT PATIENTS ONLY. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids.

OxyContin TABLETS ARE TO BE SWALLOWED WHOLE AND ARE NOT TO BE BROKEN, CHEWED, OR CRUSHED. TAKING BROKEN, CHEWED, OR CRUSHED OxyContin TABLETS LEADS TO RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF OXYCODONE.

Full prescribing information for OxyContin is attached as Exhibit B-4.